

## 510(k) Summary

JUN 23 2006

**Submitter's Name/Address**

Abbott Laboratories  
1921 Hurd Drive  
Irving, TX 75038

**Contact Person**

Linda Morris  
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Regulatory Affairs  
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**Date of Preparation of this Summary:**

April 26, 2006

**Device Trade or Proprietary Name:**

Creatinine

**Device Common/Usual Name or  
Classification Name:**

Creatinine

**Classification Number/Class:**

Class II 862.1125

**Product Code:**

CGX

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k061193

**Test Description:**

Creatinine is an in vitro diagnostic assay for the quantitative analysis of creatinine in human serum, plasma, or urine. At an alkaline pH, creatinine in the sample reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the concentration of creatinine in the sample.

**Substantial Equivalence:**

The Creatinine assay is substantially equivalent to the Roche Creatinine assay (K941837) on the Hitachi 917 Analyzer. Both assays yield similar Performance Characteristics.

**Similarities:**

- Both assays can be used for the quantitation of creatinine.
- Both assays yield similar results.
- Both assays are based on the modified Jaffe (creatinine alkaline picrate) methodology.
- Both assays use serum, plasma, and urine

**Differences:**

None

**Intended Use:**

The Creatinine assay is used for the quantitation of creatinine in human serum, plasma, or urine.

**Performance Characteristics:**

Comparative performance studies were conducted using the AEROSSET<sup>®</sup> System. The Creatinine assay method comparison yielded acceptable correlation with the Creatinine assay on the Hitachi 917 Analyzer. The AEROSSET System showed a correlation coefficient of 0.9996, slope of 0.98, and Y-intercept of – 0.19 mg/dL for the serum application and a correlation coefficient of 0.9992, slope of 0.94, and Y-intercept of – 3.66 mg/dL for the urine application when compared to the Hitachi 917 Analyzer. The ARCHITECT c8000 System showed a correlation coefficient of 0.9993, slope of 0.96, and Y-intercept of – 0.24 mg/dL for the serum application and a correlation coefficient of 0.9990, slope of 0.93, and Y-intercept of – 4.16 mg/dL for the urine application when compared to the Hitachi 917 Analyzer. The ARCHITECT c8000 System showed a correlation coefficient of 0.9996, slope

of 0.98, and Y-intercept of  $-0.06$  mg/dL for the serum application and a correlation coefficient of 0.9997, slope of 0.99, and Y-intercept of  $-0.51$  mg/dL for the urine application when compared to the AEROSET System. The Creatinine assay method comparison yielded acceptable correlation between the AEROSET System and the ARCHITECT c8000 System.

Precision studies were conducted using the Creatinine assay. On the AEROSET System, the total %CV for Level 1 is 4.95%, and Level 2 is 3.18% for the serum application and the total %CV for Level 1 is 2.41%, and Level 2 is 2.41% for the urine application. On the ARCHITECT c8000 System, the total %CV for Level 1 is 3.10%, and Level 2 is 1.54% for the serum application and the total %CV for Level 1 is 0.94%, and Level 2 is 0.99% for the urine application.

The Creatinine assay is linear from 0.20 to 37.00 mg/dL for the serum application.

The Creatinine assay is linear from 5.0 to 740.0 mg/dL for the urine application. The limit of quantitation (sensitivity) of the Creatinine assay is 0.10 mg/dL for the serum application, and 2.0 mg/dL for the urine application.

These data demonstrate that the performance of the Creatinine assay is substantially equivalent to the performance of the Creatinine assay on the Hitachi 917 Analyzer.

#### **Conclusion:**

The Creatinine assay on the AEROSET and the ARCHITECT c8000 Systems is substantially equivalent to the Roche Creatinine assay on the Hitachi 917 Analyzer as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Ms. Linda Morris  
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ADD Regulatory Affairs  
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Irving, TX 75038

**JUN 23 2006**

Re: k061193  
Trade/Device Name: Abbott Clinical Chemistry Creatinine  
Regulation Number: 21 CFR§862.1225  
Regulation Name: Creatine test system  
Regulatory Class: Class II  
Product Code: CGX  
Dated: April 26, 2006  
Received: April 28, 2006

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

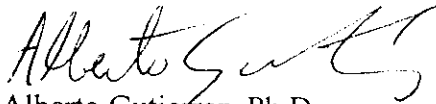
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 061193

Device Name: Abbott Clinical Chemistry Creatinine

### Indications For Use:

A creatinine test system is a device intended to measure creatinine levels in serum, plasma, and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use   X  

AND/OR

Over-The-Counter Use

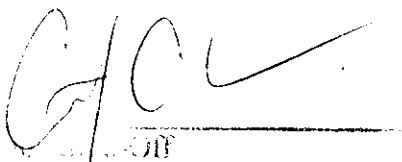
(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Office of In Vitro Diagnostic  
Evaluation and Safety

K061193

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